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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,664	03/20/2006	Jonathan Robert Rhoades	3717519.00043	4631

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
03/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,664	RHOADES ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13,16-21,24 and 27-31* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *12,13,16-21 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2010 and March 1, 2010 has been entered.

Detailed Action

This office action is a response to applicant's communication submitted January 28, 2010 and resubmitted March 1, 2010 wherein claims 12, 16, 18, 19, 21, 28, 29, and 31 are amended. This application is a national stage application of PCT/EP04/10469, filed September 17, 2004, which claims priority to foreign application GB0321966.1, filed September 19, 2003.

Claims 12, 13, 16-21, 24, and 27-31 are pending in this application.

Claim 27 is withdrawn from consideration as belonging to a non-elected invention.

Claims 12, 13, 16-21, 24, and 28-31 as amended are examined on the merits herein.

Applicant's amendment, submitted March 1, 2010, with respect to the rejection of instant claims 12, 13, 16-18, and 28-30 under 35 USC 103(a) for being obvious over

Patrick et al. in view of Tomita et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to remove lactoferrin as a second active agent. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 1, 2010, with respect to the rejection of instant claims 12, 13, 16-21, and 28-30 under 35 USC 103(a) for being obvious over Tuohy et al. in view of Tomita et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to remove lactoferrin as a second active agent from claims 12 ,13, 16-18 and 28-30 and to require a saccharide other than partially hydrolyzed guar gum in claims 19-21. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 1, 2010, with respect to the rejection of instant claims 12, 13, 16-18, and 28-30 under 35 USC 103(a) for being obvious over Tuohy et al. in view of Russell et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to remove lactoferrin as a second active agent. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13, 16-18, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (Reference included with PTO-892) in view of Bombardelli et al. (US patent 6429202, cited in PTO-892) in view of the Merck Manual of Diagnosis and Therapy, Seventeenth Edition. (Reference included with PTO-892, herein referred to as Merck)

Takahashi et al. discloses a study of the effect on human subjects of consuming a diet containing partially hydrolyzed guar gum. (p. 650 fourth paragraph and table 1) The partially hydrolyzed guar gum diet resulted in an 11% reduction in total serum cholesterol. (p. 654 first paragraph and table 5) Takahashi et al. does not disclose making a composition comprising a partially hydrolyzed guar gum and a

proanthocyanidin, or a method comprising administering such a composition to a human.

Bombardelli et al. discloses phospholipid complexes of proanthocyanidin A2 which exert antiatherosclerotic activity. (column 1 lines 50-67)

Merck discloses that abnormal serum lipid levels are a risk factor for atherosclerosis. (p. 1656 left column last paragraph - right column first paragraph) Merck also discloses that lowering cholesterol levels can slow progression or reduce regression of atherosclerosis. (p. 1657 right column third paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a composition comprising the partially hydrolyzed guar gum described by Takahashi et al. and further comprising proanthocyanidins, and to administer the composition to human subjects at risk for or suffering from atherosclerosis. One of ordinary skill in the art would have been motivated to do so because Merck discloses that lowering cholesterol is useful for treating or inhibiting atherosclerosis. One of ordinary skill in the art would reasonably have expected success because it is ordinary and routine in the art to combine two compounds known to be useful for the same purpose into a third composition directed to the same purpose.

Regarding the method described in instant claim 18, the subject range, "a mammal" is seen to encompass any mammal who could reasonably be at risk for adhesion or invasion of pathogenic bacteria, and is not restricted to only those mammals actually infected at the present time.

Regarding the specific range of about 2.5-10% of partially hydrolyzed guar gum, one of ordinary skill in the art would have reasonably been able to adjust the amounts of PHGG and inactive ingredients in the composition to arrive at an optimum value. Doing so would be within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Droitte et al. (Application EP1010372, reference included with PTO-892)

La Droitte et al. discloses a food composition comprising a probiotic microorganism and a prebiotic component. (p. 2 paragraph 0001) The probiotic can include one of several species of *Bifidobacterium*. (p. 2 paragraph 0009) The prebiotic component is preferably an oligosaccharide such as an isomaltooligosaccharide. (p. 3 paragraph 0016) These compositions cause the probiotic bacteria to outcompete pathogenic intestinal bacteria and can reduce incidence of constipation or diarrhea. (p. 3 paragraph 0028)La Droitte et al. does not specifically disclose a method comprising administering such a composition to a subject having a pathogenic bacteria associated enteric diarrheal disorder. La Droitte et al. does not specifically disclose a composition wherein the composition comprises about 2.5-10% of the isomaltooligosaccharide.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer a baked good containing an isomaltooligosaccharide according to La Droitte et al. to a subject suffering from a pathogenic bacteria associated enteric diarrheal disorder. One of ordinary skill in the art would have been motivated to do so

and would have reasonably expected success because La Droitte et al. already discloses that these compositions can be administered to reduce pathogenic bacteria and treat diarrheal disorders.

Regarding the specific range of about 2.5-10% of partially hydrolyzed guar gum, one of ordinary skill in the art would have reasonably been able to adjust the amounts of PHGG and inactive ingredients in the composition to arrive at an optimum value. Doing so would be within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over La Droitte et al. as applied to claims 19 and 20 above, and further in view of Tuohy et al. (Reference of record in previous action)

The disclosure of La Droitte et al. is discussed above. La Droitte et al. does not disclose a method wherein the composition further comprises partially hydrolyzed guar gum.

Tuohy et al. discloses a study of the effects of PHGG (partially hydrolyzed guar gum) and FOS (fructooligosaccharide) on gut microflora in humans. (p. 342, right column second paragraph - p. 343 right column first paragraph) The PHGG was administered as biscuits that contained 11% PHGG. Subjects receiving the prebiotic treatment increased the levels of *bifidobacteria* in their intestines. (p. 344, left column and tables 1 and 2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add partially hydrolyzed guar gum to the food compositions described by La Droitte et al. One of ordinary skill in the art would have been motivated to do so because Tuohy et al. discloses that PHGG acts as a prebiotic to support growth of *Bifidobacteria* in a subject's intestines. One of ordinary skill in the art would have reasonably expected success because La Droitte et al. already discloses a variety of different prebiotic substances for use in the compositions.

Therefore the invention taken as a whole is *prima facie* obvious.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Reference of record in previous action) in view of Lesens et al. (US patent 6399124, of record in previous action)

Lee et al. discloses the growth of bacterial cultures in the presence of chitooligosaccharides. (p. 320 left column paragraph 4 - right column paragraph 2) The chitooligosaccharides stimulate the growth of bifidobacteria. (p. 321 right paragraph section 3.3) Lee et al. does not disclose a method of treating pathogenic bacteria-associated disorders in a mammal by administering a composition comprising 1-15g of chito-oligosaccharides.

Lesens et al. discloses a frozen desert containing probiotic bacteria for treating gastrointestinal disorders. (column 2 lines 20-36) The probiotic microorganism can include several species of *Bifidobacteria*. (column 2 lines 44-65) The bacteria are capable of excluding pathogenic bacteria from intestinal cells and allowing the immune system to react more strongly against external aggression. (column 3 lines 1-13) The frozen dessert contains a support or coating comprising fibers, for example oligosaccharides, which promote the growth of the probiotic. (column 4 lines 30-52) Fibers can be present in an amount up to 10g. (column 5 lines 15-29) In an example, (column 8 example 1) an ice cream according to the invention is seen to contain 8% fat and 36.38% total dry solids, of which 28.38 must then be non-fat dry solids. Assuming

a value of 9 kcal/g for the fat and 4 kcal/g for the other dry solids, (as carbohydrate or protein) the upper limit of the total caloric value of this ice cream would be about 184 kcal per 100g. In column 10 lines 32-40 of Lesens et al., a subject is described as eating about 100g of the ice cream, or about 184 kcal, per day. In column 13 lines 15-42, an ice cream sandwich comprising about 50g of ice cream and two 10.5g biscuits is described. In table 8 the biscuit recipe is described as containing 8g of fat per 100g. Even assuming that the entire remainder of the biscuit contains 4 kcal/g as carbohydrate, 21g of biscuits would comprise about 92 kcal. In combination with 50g of ice cream, the total caloric value of one ice cream sandwich would again be abut 184 kcal. Therefore a serving of this ice cream, in either embodiment, contains far less than 1000 kcal.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use from 1-10g of the chito-oligosaccharides of Lee et al. in a bifidobacteria-containing probiotic composition according to Lesens et al., and to administer this composition to a patient suffering from a bacterial enteric infection. One of ordinary skill in the art would have been motivated to do so because Lesens et al. already discloses that the compositions contain up to 10g of prebiotic fibers to promote the growth of the probiotic organism. One of ordinary skill in the art would reasonably have expected success because Lesens et al. discloses that these formulations can protect intestinal cells against pathogenic bacteria.

Regarding the limitation that the composition have a caloric value of less than about 1000 kcal, Lesens et al. discloses several ice cream compositions having a

caloric value of significantly less than 1000 kcal. One of ordinary skill in the art would have reasonably been motivated to prepare the invention as any of these compositions and would have reasonably expected success in view of the fact that the reference provides detailed instructions for doing so.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted March 1, 2010, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims as amended require that the composition contain less than 1000 kcal, and that Lesens et al. fails to consider a composition having a caloric content of less than 1000 kcal. However, as discussed above, this statement is incorrect and Lesens specifically discloses several ice cream products having a caloric content of about 184 kcal, which is low enough to meet the new claim limitation. Therefore the rejection is deemed proper and maintained.

Conclusion

Claims 12, 13, 16-21, and 28-31 are rejected. Claim 24 is seen to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
3/22/2010